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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,215	02/23/2004	Craig P. Roberts	51283-0002	8829
45200	7590	03/06/2006	EXAMINER	
PRESTON GATES & ELLIS LLP 1900 MAIN STREET, SUITE 600 IRVINE, CA 92614-7319			KIM, SUN U	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/785,215

Applicant(s)

ROBERTS ET AL.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/4/05, 10/3/05</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS filed 11/21/05</u> . |

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1. The disclosure is objected to because of the following informalities: “BRIEF DESCRIPTION OF THE FIGURES” in paragraph [0033] should be changed to “BRIEF DESCRIPTION OF THE DRAWINGS”. A unit “ μ M” in paragraph [0054, 0056, 0064] should be changed to “ μ m” for a correct unit for length.

Appropriate correction is required.

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see paragraph [0053]: see <http://www.bb Braun.com/> for details). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

3. Claims 5 and 13 are objected to because of the following informalities: A correct unit for a length is “ μ m” and not “ μ M”. Appropriate correction is required.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4, 6 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4, 6 and 12 contains the trademark/trade name Amberlite XAD-7HP or Amberchrom GC300C. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or

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trade name does not identify or describe the goods associated with the trademark or trade name.

In the present case, the trademark/trade name is used to identify/describe non-ionic aliphatic ester resin or non-ionic polystyrene divinyl benzene resin and, accordingly, the identification/description is indefinite.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 9-10 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by European Patent Application No. 787 500 A1 (hereinafter referred to as EP '500). EP '500 teaches a method and a device for extracorporeal removal of toxins comprising a plasma filter (5), uncoated activated carbon in a first housing (11) and hydrophobic i.e. non-ionic polystyrene resins including styrene-methacrylate resin i.e. aliphatic ester resin and copolymer divinylbenzene-polystyrene resin in a second housing (12) wherein activated charcoal is a form of activated carbon (see figure 1; abstract; page 2, lines 1-7; page 2, line 25 – page 3, line 3; page 3, line 35 – page 4, line 23; page 5, lines 37-40).

8. Claims 1-2, 9 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Matson et al '516 (US Pat. No. 6,287,516). Matson et al '516 teach a method and a device for extracorporeal removal of toxins comprising a hemofilter (102) or a plasma filter, uncoated or coated activated charcoal in a first chamber or a first housing and a non-ionic resins including polymethylmethacrylate resin i.e. aliphatic ester resin in a second chamber or a second housing wherein blood is removed from patient and circulated through above apparatus in an

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extracorporeal circuit (see figures 1-3A, 5C; abstract; col. 6, lines 8-67; col. 10, lines 37-45; col. 11, lines 18-63; col. 13, line 1 – col. 14, line 44; col. 17, lines 1-27).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 3-6 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '500. EP '500 teaches a device for extracorporeal removal of toxins in above paragraph 7. EP '500 further teaches that there are known hydrophobic resins commercially available as AMBERCHROM (styrene-methacrylate resin) and AMBERLITE (copolymer divinylbenzene-polystyrene resin) manufactured by ROHM & HAAS that would be capable of retaining cytokines e.g. toxin wherein such resins have a granule size of 20 –100 microns and a porosity of 100 to 300 Angstrom for AMBERCHROM and a granule size of 250 – 350 microns and a porosity of 130 –150 Angstroms for AMBERLITE (see page 3, line 49 – page 4, line 3). Claims 3-6 and 11-13 essentially differ from the device of EP '500 in reciting non-ionic aliphatic ester

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resin or non-ionic polystyrene divinyl benzene resin with claimed average surface area, average pore size and mean particle diameter. Claimed average surface area, average pore size and mean particle diameter are result effective variables in obtaining adsorptivity of toxins in plasma. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize average surface area, average pore size and mean particle diameter from known series of commercially available hydrophobic resins manufactured by ROHM&HASS, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

12. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '500 as applied to claims 1, 9-10 above, and further in view of Okazaki et al (US Pat. No. 4,988,569). EP '500 teaches a device for extracorporeal removal of toxins in above paragraph 7. EP '500 teaches the use of an uncoated activated carbon in a hemoperfusion cartridge (see page 4, lines 18-22). Claims 7 and 14 essentially differ from the device of EP '500 in reciting an uncoated coconut shell granule charcoal. Okazaki et al teach an adsorbent for hemoperfusion comprising activated granular carbon obtained from coconut charcoal (see col. 3, lines 54-65). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include known activated carbon derived from coconut charcoal for the activated carbon in the device of EP '500 as suitable adsorbent for hemoperfusion.

13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '500 as applied to claim 1 above, and further in view of Wallace (US Pat. No. 4,209,392). EP '500 teaches a device for extracorporeal removal of toxins in above paragraph 7. Claim 8 essentially differs from the device of EP '500 in reciting a particle filter downstream of the toxin removal device.

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Wallace teaches a device for extracorporeal removal of toxin comprising a particulates filter downstream of sorbent cartridge to remove any bacteria, pyrogens and sorbents fines which could lead to the formation of microemboli (see figure 1; col. 5, lines 4-21). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a particle filter downstream of sorbents (11, 12) to effectively remove any bacteria, pyrogens and sorbents fines to prevent the formation of microemboli which are harmful to patient's blood stream.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-14 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-4, 8-13 and 15-16 of copending Application No. 11/157,344. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 3-4, 8-13 and 15-16 of copending Application No. 11/157,344 fully suggests claims 1-14 and 17 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 15-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 8-9 of copending Application No. 11/157,344 in view of EP '500. Claims 1, 3 and 8-9 of copending Application No. 11/157,344 teaches an extracorporeal system comprising a plasma filter and an adsorptive device comprising one or more adsorbents of activated carbon and non-ionic exchange resin including non-ionic aliphatic ester resin or non-ionic polystyrene divinyl benzene resin. Claims 15-16 of instant application essentially differ from claims 1, 3 and 8-9 of copending Application No. 11/157,344 in reciting activated charcoal contained in a first housing and a second housing having at least one non-ionic resin disposed therein. EP '500 teaches a first housing (11) containing activated carbon and a second housing (12) containing hydrophobic or non-ionic resin (see page 4, lines 18-21). It would be obvious to a person of ordinary skill in the art to provide first and second housing for separately housing activated charcoal and non-ionic resin.

This is a provisional obviousness-type double patenting rejection.

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17. Claim 18 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of copending Application No. 11/157,344 in view of EP '500. Claim 16 of copending Application No. 11/157,344 teaches a method of removing toxins from blood comprising circulating the venous blood of a patient through an extracorporeal circuit having an adsorptive toxin removal device disposed therein wherein the toxin removal device comprises activated carbon and at least one non-ionic resin. Claim 18 of instant application essentially differ from claim 16 of copending Application No. 11/157,344 in reciting a non-ionic resin being non-ionic aliphatic ester resin or non-ionic polystyrene divinyl benzene resin or a combination thereof. EP '500 teaches a hydrophobic resin or non-ionic resin comprising styrene-methacrylate resin i.e. non-ionic aliphatic ester resin or copolymer divinylbenzene-polystyrene resin for removal of toxin e.g. cytokines (see page 3, lines 49-56). It would be obvious to a person of ordinary skill in the art to provide known non-ionic resin being non-ionic aliphatic ester resin or non-ionic polystyrene divinyl benzene in the method of claim 16 of copending Application No. 11/157,344 to remove toxins such as cytokines .

This is a provisional obviousness-type double patenting rejection.


18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat. Application Publication No. 2005/0281809 is a published application of application no. 11/157,344.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 8:30 A.M. to 5:00 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


John Kim
Primary Examiner
Art Unit 1723

J. Kim
February 28, 2006